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Attachment 4
510(k) Summary

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Susan R. Pool Manager, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Information:	E-mail: pools@bsci.com Phone: 408.895.3608 Fax: 408.895.2202
Device Common Name	Electrosurgical Probe
Device Proprietary Name	Cobra® Cooled Surgical Probe
Device Classification	21 CFR § 878.4400, class II, product code GEI
Predicate Device	Electrosurgical Probe
Predicate Device Manufacturer(s)	Boston Scientific Corporation/EP Technologies, Inc.
Predicate Device Proprietary Name(s)	Cobra® Surgical Probe
Predicate Device Classification Number	Class II
Predicate Device Classification(s)	21 CFR § 878.4400, product code GEI

Date Summary Was Prepared:

March 28, 2002

Description of the Device:

The Boston Scientific Corporation Surgical Probe is a sterile, single use electrosurgical device intended to be used to coagulate soft tissues. The surgical probe transmits radiofrequency energy from electrodes which are connected to an Electrosurgical unit (non-sterile; re-useable) through an Instrument Cable (sterile; re-useable).

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Intended Use:

The Probe is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissues to produce hemostasis.

Comparison to Predicate Device:

	Predicate Device	Modified Device
510(k) Reference	K981981; K010956	Current Submission
Intended Use	Coagulation of tissue	Same
Device Description	Electrosurgical Probe	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	Boston Scientific Corporation/EP Technologies, Inc.	Same
Device Classification	Class II, 21 CFR §878.4400, code GEI	Same

Summary of the Non-clinical Data:

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Specifically, non-clinical tests conducted for the Device included Fluid Path Integrity, Bond Joint Tensile Strength, Bond Joint Torsional Strength, Distal Section Fatigue, Shaft to Handle Tensile Strength, Biocompatibility and, both acute and chronic, *In vivo* performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2002

Ms. Susan Pool
Regulatory Manager
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K021046
Trade/Device Name: Cobra Cooled Surgical Probe, Model 1596X
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 28, 2002
Received: April 1, 2002

Dear Ms. Pool:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Intended Use Statement

510(k) Number (if known): K021046

Device Name: Cobra® Cooled Surgical Probe

Indication for Use:

The Probe is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissues to produce hemostasis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR §801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021046